



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2015-C-1154]

E. & J. Gallo Winery; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by E. & J. Gallo Winery, proposing that the color additive regulations be amended to provide for the safe use of mica-based pearlescent pigments as color additives in certain distilled spirits.

DATES: The color additive petition was filed on March 19, 2015.

FOR FURTHER INFORMATION CONTACT: Salome Bhagan, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-3041.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 5C0302), submitted by E. & J. Gallo Winery, c/o Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111. The petition proposes to amend the color additive regulations in § 73.350 Mica-based pearlescent pigments (21 CFR 73.350) to

provide for the safe use of mica-based pearlescent pigments at a level of up to 0.07 percent by weight in distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume, and to remove the current exclusion for distilled spirit mixtures containing more than 5 percent wine on a proof gallon basis.

We have determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 15, 2015.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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